Amendments to the Claims

Listing of Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Canceled)

2. (Previously Presented): An in vitro method for diagnosing a subject as having or as being at risk for having a thrombotic disorder associated with activated protein C (APC)-resistant factor V or Va, wherein the subject is presently on an oral anticoagulant regimen, the method comprising:

a) contacting a test sample comprising a coagulation factor V or Va-containing specimen from the subject with a procoagulant reagent, factor V-deficient plasma to provide coagulation factors other than factors V or Va, calcium present in a concentration from about 5 mM to 15 mM, and APC present at from about 100 ng/ml to 10 ug/ml in a test reaction; and

b) comparing the clotting time for the test reaction to the clotting time for a control reaction carried out under the same conditions as the test reaction, but with a control sample comprising a coagulation factor V or Va-containing specimen from an individual not having or not at risk of having a thrombotic disorder associated with APC-resistant factor V or Va, wherein:

i) detection of a decreased clotting time in the test reaction relative to the control reaction indicates a diagnosis of a thrombotic disorder associated with APC-resistant factor V or Va; and

ii) detection of a similar clotting time in the test reaction relative to the control reaction indicates that the subject does not have or is not at risk of developing a thrombotic disorder associated with APC-resistant factor V or Va.

3. (Previously Presented): The method of claim 2, wherein the specimen from the subject is previously frozen plasma.

4. (Previously Presented): The method of claim 2, wherein the thrombotic disorder is thrombophilia.

5. (Previously Presented): The method of claim 2, wherein the thrombotic disorder is due to a factor V mutation.

6. (Previously Presented): The method of claim 5, wherein the mutation results in a change from arginine to glutamine at position 506 of factor V.

7. (Previously Presented): The method of claim 2, wherein the procoagulant reagent comprises tissue factor.

8. (Previously Presented): The method of claim 2, wherein the procoagulant reagent comprises a phospholipid.

9. (Previously Presented): The method of claim 8, wherein the phospholipid is present at a concentration of about 5-100 uM in the test reaction.

10. (Previously Presented): The method of claim 8, wherein the phospholipid is present at a concentration of about 10-50 uM in the test reaction.

11. (Previously Presented): The method of claim 2, wherein the procoagulant reagent comprises an activator of the intrinsic coagulation pathway.

12. (Previously Presented): The method of claim 11, wherein the activator is a clotting factor selected from the group consisting of factor Xa, factor IXa, factor XIa and factor XIIa.

13. (Previously Presented): The method of claim 2, wherein the procoagulant is a reagent selected from the group consisting of kallikrein, Russell's viper venom, micronized silica particles, ellagic acid, sulfatides, kaolin, and tissue thromboplastin.

14. (Previously Presented): The method of claim 2 wherein the specimen from the subject is diluted in a physiologically balanced buffer.

15. (Previously Presented): The method of claim 2, wherein the APC in the test reaction is present at from about 200 ng/ml to 1 ug/ml.

16. (New): The method of claim 2, wherein the anticoagulant is heparin.

17. (New): The method of claim 2, further comprising setting up a no-APC test reaction, carried out under the same conditions as the test reaction except that no APC is added to the reaction, wherein a clotting time for the test reaction that is similar to, or faster than, a clotting time for the no-APC reaction is indicative of a subject having a thrombotic disorder associated with a homozygous mutation from arginine to glutamine at position 506 of factor V.

18. (New): An in vitro method for diagnosing a subject as having or as being at risk for having a thrombotic disorder associated with activated protein C (APC)-resistant factor V or Va, wherein the subject is presently on an oral anticoagulant regimen, the method comprising:

a) contacting a test sample comprising a coagulation factor V or Va-containing specimen from the subject with a procoagulant reagent, factor V-deficient plasma to provide coagulation factors other than factors V or Va, calcium sufficient to initiate clotting, and APC; and

b) comparing the clotting time for the test reaction to the clotting time for a no-APC control reaction carried out under the same conditions as the test reaction, but without adding APC, wherein detection of a similar clotting time or faster clotting time in the test reaction relative to the no-APC control reaction indicates a diagnosis of a thrombotic disorder associated with APC-resistant factor V or Va.

19. (New): The method of claim 18, wherein a clotting time for the test reaction that is faster than, a clotting time for the no-APC reaction is indicative of a subject having a thrombotic disorder associated with a homozygous mutation in factor V or Va rendering the factor APC-resistant.

20. (New): The method of claim 19, wherein the mutation occurs at position 506 of factor V.

21. (New): The method of claim 20, wherein the mutation is a change from arginine to glutamine at position 506 of factor V.

22. (New): The method of claim 2, wherein an anticoagulant neutralization step is not performed before performing the method.